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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,310	05/31/2001	Robert Ainsworth	3764.P180	4544

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EXAMINER

JUNG, WILLIAM C

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,310

Applicant(s)

AINSWORTH ET AL.

Examiner

William Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-21, 26, 27, 32-35 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-21, 26, 27, 32-35 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed October 18, 2004 have been fully considered but they are not persuasive.

Examiner respectfully disagrees with the Applicant's assertion that the amended claims 1, 15, 26, 32, 34, and 44 where limitation of as least one optical fiber disposed within a sheath and disposed within the intravascular device, the a least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath is distinct from McGee et al. McGee et al, device as shown in figure 5A has sheath 20 where the optical fiber is disposed within the shear (where in the figure 5A, the sheath has been inflated). Further more, the shear 20 is bonded to the element 48. Therefore, the added limitations in claims 1, 15, 26, 32, 34, and 44 do not overcome McGee et al reference. Therefore, the rejection stands from the previous Office Action dated July 14, 2004 and is repeated below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5-9, 11-13, 15-19, 21-24, 26, 28-30, 32, 34, 36, and 40-47 are rejected under 35 U.S.C. 102(b) as being anticipated by *McGee et al* (US 5,752,518).

Claims 1, 15, 22, 26, 28, 40, and 44: McGee et al anticipate all claimed elements in claims 1, 15, 22, 26, 28, 40, and 44: McGee et al disclose an intravascular catheter 10

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comprising structure 20 to perform diagnostic imaging and therapeutical treatment with sheathed optical fibers 44 disposed through the intravascular catheter. In addition, a sheath is slidably disposed over the catheter shaft and an intraluminal gap extending longitudinally along the elongated member. Furthermore, the control of the intravascular catheter is achieved with guidewire (col. 5, line 30-34). The imaging using either ultrasound transducer or fiber optic assembly can be used before and after the treatment to assess treatment area (col. 1, lines 44-67; col. 3, line 53 – col. 4, line 39; col. 4, line 62 – col. 5, line 10). In addition, McGee et al intravascular catheter has expandable portion 64 (col. 7, lines 53-60).

Claims 32, 34, and 36: McGee et al further disclose in figure 6 where receiver & processor 57 processes the data and display on display unit 59.

Claims 2, 19, and 24: McGee et al shows in figure 4A, where the optical fiber 20 is exposed within a vasculature of a patient.

Claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35, and 39:

Claims 5, 8, 9, 13, 16, 23, 37, 38, 42, and 46: McGee et al disclose that the inflatable portion 64 is a balloon catheter disposed about a tubular inner member having a lumen to receive the optical fiber 34 (col. 7, lines 52-61). The inflatable balloon can be applied in procedure such as angioplasty, stenting and restenting (col. 3, line 62 – col. 4, line 9).

Claims 6, 7, 11, 17, 41, 43, 45, and 47: I figures 1 and 5A McGee et al shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen. In addition, figure 5A shows that the optical fiber is substantially parallel to the tubular member.

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Claims 12 and 18: As described above, McGee et al disclose the catheter where the lumen is consisting of guidewire, inflatable balloon, radiation source, atherectomy, laparoscopy, and drug delivery (col. 3, line 62 – col. 4, lines 9; col. 5, lines 40-45).

Claim 21: McGee et al disclose that the optical fiber and lumen may include radioopaque materials (col. 5, lines 40-45).

Claims 29 and 30: McGee et al disclose that the elongated member is a coil or braided member (col. 11, line 60 – col. 12, line 9; col. 15, lines 44-56).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over *McGee et al* as applied to claims 1, 2, 5, 8, 9, 11-13, 15, 19, 22-24, 26, 28, 32, 34, and 36 above, and further in view of *Morantte, Jr.* (US 4,587,972).

McGee et al substantially disclose all claimed features in claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35, and 39. However, McGee et al do not specifically disclose a measurement of vessel and blood characteristic such as hemodynamic characteristics. In *Morantte, Jr.*, an intravascular catheter is used to diagnosis and treat blood vessel by measuring hemodynamic characteristics of the blood vessel using optical source or laser energy to assess the level of treatment or therapy required (col. 4, line 42 – col. 5, lines 17). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of *Morantte*,

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Jr.'s hemodynamic characteristic measurement to assess therapy guideline using optics or laser to improve McGee et al's apparatus where it includes therapy assessment by imaging.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lxs

January 21, 2005


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